

Block-chaining in Precision HealthCare: a design research approach.

Research-in-Progress

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Abstract

The rapid development of digital healthcare brings many benefits to the healthcare industry and bio-science. Precision healthcare is considered one of the most promising directions for healthcare development. The practice of precision healthcare is based on genetic sequencing and then prescriptive and predictive analytics based on big data. However, it creates a serious issue of how to encourage the opting-in of patients so that more robust and reliable models may be built. Blockchain, as a promising, secure, transparent and “trustless” technology, may be the solution to address the concern of patients. However, to date, blockchain has not been developed for precision healthcare systems. To address this research gap, this paper proposes a blockchain-based, smart informed consent architecture using design science. The solution seeks to determine whether blockchain may be applied to precision healthcare to improve service outcomes by increasing the opting in of patients.

Keywords: digital health, security and trust, soft systems methodology.

Introduction

With the development of information and communication technologies, healthcare has entered a new era of digitalization over the past decades. Digital Healthcare is defined as healthcare practice with electronic processes and communications (Della 2001). Information and Communication Technology is used in digital health for better healthcare delivery. In the digital healthcare era, medical decision could be made upon the e-healthcare records. Healthcare service providers are giving medical suggestions basing on patients’ current and historical medical data. Some statistics show almost 90% clinical improvement due to the of the use of e-healthcare records to the medical decision (Kawamoto et al. 2005).

Precision Healthcare has emerged as an evolved personalized health service of digital healthcare. It is increasingly regarded as the most important medical approach, which provides customized healthcare including clinical decisions, treatments and products to the individual patient (Lu et al., 2014). This approach is driven by big data analysis of massive genome information, combining genetic diagnoses with personal healthcare records. Figure 1 below shows a rich picture of the eco-system of precision healthcare, drawn as part of the Soft System Methodology (SSM) (note: the SSM specifically employs hand-drawn pictures in the requirements-gathering phase).

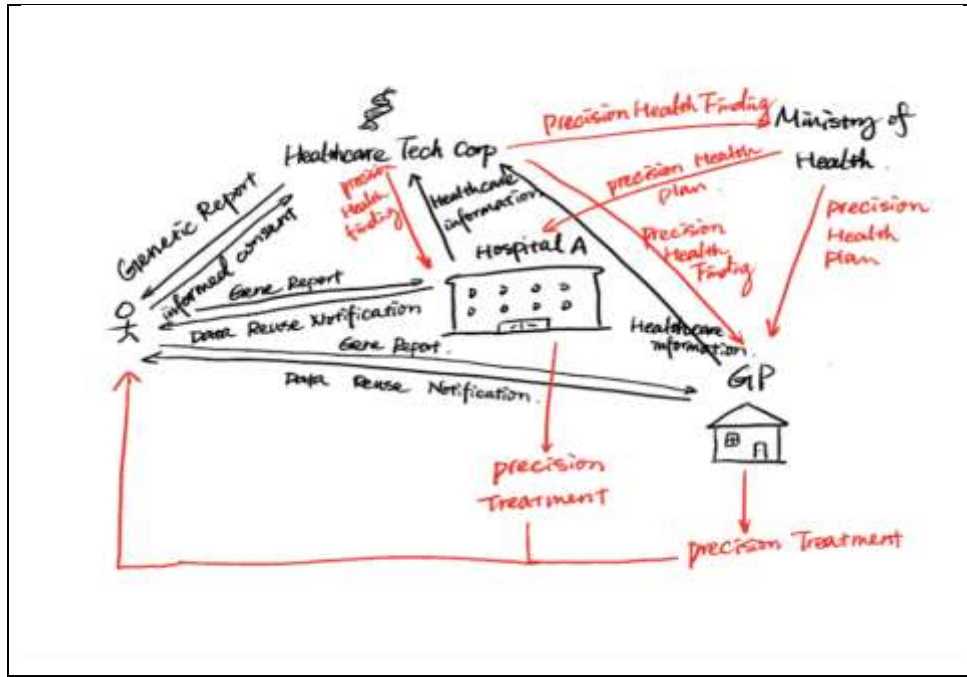


Figure 1. Eco-system of precision healthcare

Precision healthcare achieves diagnostic accuracy through the big data analysis, therefore, more data is necessary for precision healthcare delivery. But people are less willing to share sensitive data, considering such disclosure might seriously impact their privacy. Research suggests, 38% of the respondents are not willing to participate in gene testing because of their distrust of privacy protection of the gene related researches, and the strict confidentiality is the first condition before they share the genetic data (Andrews 1994; Lunshof et al. 2008). In addition, other research notes that existing fears of genetic testing include the invitation of discrimination, decrease of privacy, and other severe ethical problem if it is known by some unintended institutes or people (Fulda 2006). The concern of privacy is reasonable; patients in the precision healthcare system (PHC) now have little power to control their own information, as current precision healthcare lacks data-transparency (Colijn et al. 2017) and accountability (Das et al. 2016).

The PHC is untrustworthy for patients, when they are incapable to clearly know how their data will be used. This includes not only the subjective perceptions of patients, but the current electronic healthcare record system also does not provide a trustworthy technical environment for the patients. Evidently, research reveals that the current electronic healthcare records (EHR) system as a centralized network, may not be secure to support the operation of the PHC (McGuire et al. 2008). Furthermore, data breaches have increased steadily over the years. A study shows that more than 90% of hospitals ever experienced at least one data breach in US (P. Institute 2012). As a result of issues above, patient enrollment in PHCs has not grown. Limited patients opting in leads to the poor network effect in the precision healthcare. This means more users engaging into the network will bring a better outcome accordingly to each user, while the current situation of precision health acts oppositely, to improve the network effect of precision health to get better service level. The network needs to attract more patients opting into precision healthcare and preferring to share their sensitive data with the other stakeholders in the system. The key point here is to improve the cyber-security of precision healthcare, while enhancing the autonomy of patients to their private information. Recent research suggests that blockchain may be developed for digital healthcare ecosystems to improve their security and privacy levels (Dhillon and Hooper 2017), and it is likely that network effects would also improve healthcare service levels.

Blockchain is considered as one of the promising technologies for adoption. Many academics and professionals argue that Blockchain is the breakthrough network, which will be able to change the transaction of business in many industries. An appropriate definition of Blockchain is "a distributed ledger network using public-key cryptography to cryptographically sign transactions that are stored on

a distributed ledger, with the ledger consisting of cryptographically linked blocks of transactions" It uses mathematical techniques to encrypt and decrypt data to offer a secure and efficient solution for data management (Kshetri 2017). The advantage blockchain offers business is simply said, "save time and costs while reducing risks". It not only provides a secure environment, but also an economical approach (Sloane and Bhargav, 2017). Blockchain may also provide considerable value to the healthcare industry by providing a trust-worthy environment to improve the cyber-security and interoperability of digital healthcare ecosystems (Yue et al. 2016). Therefore, it is valuable to study whether blockchain may also be applied to precision healthcare to improve the outcomes of healthcare.

Although there are many researchers have explored the possibility of applying blockchain into digital healthcare, there are limited work referring to the practice of "precision health". Precision health is healthcare that relies on analysis of the patient's genome to provide customized, targeted treatments. Part of the problem is that low patient opt-in lead to less impactful treatments because prescriptive and predictive analytics need big data. The purpose of this study is to design a blockchain-based solution for the precision healthcare ecosystem.

Background Review

The rapid development of bio-informatics brings more types of data that are considered as evidence of diagnostic and treatment in the practice of healthcare. Recently, the use of genetic information has gained increasing attention, which uses analysis of the patient's own genome to develop treatments. With the support of genomic information, it will be possible to tailor treatment to individuals according to their genome data and other personal healthcare information. This would involve the large-scale processing and analysis of patient "Big Data" as a necessary technical foundation.

From a descriptive lens, through the analysis of gene sequencing data and the investigation of an individual's symptoms and indicators of environment and disease factors, it will be possible to associate certain disorders with genotypes and phenotypes in the patient's genome. From a predictive lens, research on genotypes and phenotypes will be references for healthcare providers to indicate what will happen to the patients and give the intervention accordingly, from a prescriptive view. The whole process will provide benefit to the individuals for them acquiring appropriate, precise treatment, which will also bring benefit for the populations by giving valuable suggestions of disease prevention upon their subsets of population, for example different races and regions.

To briefly explain the benefit of the precision healthcare, ideally, patients will be able to involve in to the whole system of precision healthcare. They are able to manage their own genetic information which they got from healthcare technology companies. They can share their genetic information with GPs or Hospitals, and the healthcare service providers are able to give more precise diagnoses, prescription, prevention suggestion and treatment to the patients according to the various evidence. On the other hand, with the consent of patients, healthcare technology companies are able to share their findings to healthcare providers for better service delivery. The Ministry of Health is also being able to get a copy for their healthcare plan of investment or other policy-making for fitting better to the population. Successful precision healthcare should benefit all the stakeholders in the system of healthcare.

Precision healthcare relies highly on "big" healthcare data analysis of the genome, which means the data source should possess good quality in these four characteristics: high volume, rich varieties, sufficient veracity, and fast velocity. Lacking of the four will lead to the failure or inaccuracy of the precision healthcare. Firstly, due to the requirements of genome analysis, it is significant to gain sufficient samples for data mining. The high volume of data will bring the decrease of the errors in the data analysis, which means the higher accuracy of the results. As healthcare is a serious issue for everyone, it is really crucial to give the most accurate result as possible through the analysis. Second, the wider the varieties of data collected is also a must in the precision healthcare. As it is known to all, the population is complex in multilevel with various groups, such as different ages, sex, and regions, which will lead to different medical phenomenon depending on their different gene. To solve this problem, wide variety collection is the only way to improve the variety of data source to cover different groups, discover the potential relationships among that and give a stable predictive model accordingly (Sedgwick 2015). Finally, because of the particularity of genetic data, timely updating data will provide

better support for the genome data analysis; the faster the phenotypes are collected, the timelier the evidence will be offered for analysis in the fast-changing healthcare industry to maximize the benefit (Frey et al. 2014).

Research Method

A PHC is a complicated system that involves multiple stakeholders. The Soft System Methodology (SSM) is a tried and tested method of action research if the goal is to clarify ill-defined system requirements (Checkland and Scholes 1999), and therefore it is appropriate for the domain. A key feature of the SSM is the expression of key requirements through the drawing of rich pictures, which follow the stages of the model's root definition and model's framework design (Checkland and Scholes 1999). The resulting model is then validated by testing in a production environment, which in this case means conducting stakeholder interviews that examine whether the proposed blockchain-based system can improve the service levels and reduce costs. The expert interview is an effective method for validating untested system features and requirements (Libakova 2015). Compared to other methods, the data collected through expert interviews is more reliable and valuable because of the professionalism and high competency of the experts (Dorussen et al. 2005). The result of applying the SSM techniques, in this case, will be to design the proposed blockchain-based system for precision healthcare so that it can deliver a high service level and low-cost outcome.

Overall, the SSM consists of seven steps. This research is structured as starting from a problematic consideration based on the current situation of precision healthcare. Then, these aforementioned problems, which hinder patients from opting-in to PHC are expressed in hand-drawing "rich pictures". Third, the key root of the system model will be defined, so will the design rules. Fourth, the conceptual design model will be proposed with being named in root definition. Sixth, the model will be validated through interviews. The model validation is for examining if the design is relevant to the real world problems (Checkland, 1995). The last two steps will make design changes and actions according to the result of validation for systematically desire and feasibility (Checkland & Scholes, 1999).

As mentioned above, SSM calls for hand-drawn pictures as an aid to specify system requirements, in this case, the current context of precision healthcare in New Zealand. In this manner, the researcher and system stakeholders collaboratively engage to depict real system problems in graphical form. The "rich pictures" of Figure 2 and Figure 3 depict two typical scenarios of precision healthcare. The rich pictures depict the problem from the perspective of the system stakeholders. This may be used as a means of obtaining a shared "world view" as well as an understanding of a "problematic situation" for which a systems solution is sought. A description of the method and techniques maybe found in several other resources and is beyond the coverage of this paper.

Major Challenges in Precision Healthcare

In addition to the above, the demands placed on precision healthcare for "Big Data" - a large volume of high-quality data - is still insufficient. The main reason behind this is the patients' distrust of the current PHCs, which discourages them from participating in the project and providing their personal information. However, trustworthy systems are known to reduce the patients' concern and increase their willingness to participate in the precision healthcare (Brodersen et al. 2016). There are three issues that should be addressed in order to produce a system that is perceived by patients to be trustworthy.

Cyber-Security

System security is one of the most significant issues for any information system, and especially for healthcare information systems because of the confidential nature of the data. Cyber security in this context is defined as the protection of computer systems, including software, information, and hardware, from harm through the restriction of network access, physical access, code injection and data (Schatz et al. 2017). Genome data is particularly sensitive because it not only contains information about an individual, but also potentially about the individual's entire family, race, or "home" region. Currently, most healthcare providers use centralized systems that store all their data in the cloud or a server. Given the more sensitive nature of data in PHCs, the centralized storage architecture (e.g.

centralized cloud storage) faces both a higher risk and greater potential damages in the case of a security breach as compared to decentralized architecture (Kupwade and Seshadri, 2014). In summary, the security of centralized systems is insufficient given the high demands for security and the protection of patients' privacy in PHCs.

Many of these threats may be mitigated by a blockchain system. First of all, patients' identities are more easily safeguarded by the anonymity of the blockchain. Secondly, the distributed architecture of a blockchain healthcare information system would make it very difficult to compromise the entire system, by comparison to centralized systems.

Data Transparency

Data transparency is also a key issue for PHCs because of the need for accountability with respect to how the patient's data is handled. In this context, data transparency refers to the openness data collection and data processing practices and procedures (Life, 1994). In modern healthcare systems, the collection and use of data is very hard for stakeholders, especially patients, to trace. Therefore, data transparency is a necessary prerequisite to building trust with the patients, and especially more so for PHCs. In a PHC with data transparency, the increased reliability and visibility of the data will enable stakeholders to build a more collaborative and trusting environment, and patients will be able to determine whether private genome-related data are being used appropriately (Kelman et al 2002).

Blockchain technology has the capability to support data transparency while preserving anonymity. For example, blockchain applications may be developed that support completely anonymous and transparent doctor-patient collaborations. It is also possible to give patients discretion over the use of their data by third parties.

Accountability

Perhaps most importantly, healthcare systems in general, and PHCs in particular should provide accountability for all stakeholders and patients. In this context, accountability is defined as the capability to determine who is using the system, and for what purposes the system is being used, for example, providing the ability for patients and the stakeholders to determine who is responsible for any given transaction (Mashima and Ahamad, 2012).

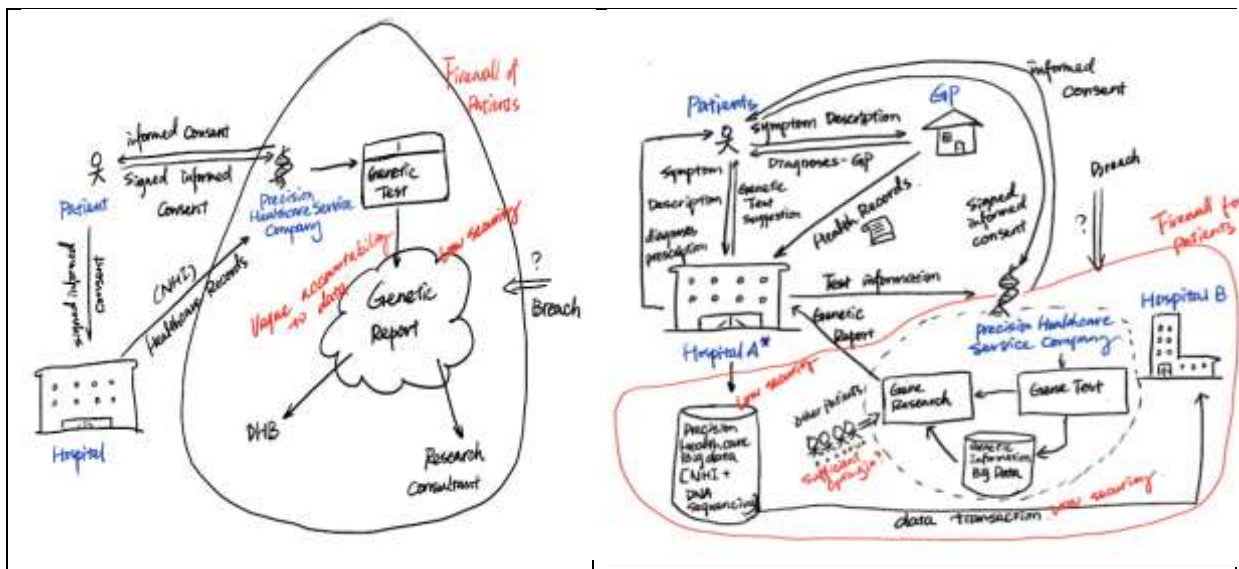


Figure 2. Rich Picture of model-building in precision healthcare

Figure 3. Rich picture of clinical consultation using precision healthcare

This is a problem in many modern healthcare systems because the centralized system architecture often does not permit access to the parties that need access where questions of accountability are concerned. Furthermore, it is easy for authorities in a centralized system to cover up failures of accountability. Blockchain's ability to maintain an immutable record of transactions would support the goal of

accountability by preserving information of all system activity, including the people or entities taking actions, the actions taken, and the outcomes. Also, blockchain's decentralized architecture would make it almost impossible for anyone to cover up a failure of accountability.

To specify the problematic situation of current precision healthcare in the context of New Zealand, rich pictures will help articulate the issues in the real world. The rich pictures of Figure 2 and Figure 3 depict two typical scenarios of precision healthcare as it is practiced in New Zealand and elsewhere (Colijn et al., 2017; Das et al., 2016; Frey et al., 2014).

Design of Block-chained Precision Healthcare

From a security standpoint, research shows that systems with centralized data warehouse are more vulnerable to technical attacks, resulting in data loss. For improving the security of a healthcare system, a distributed model is suggested where the healthcare service provider replicates healthcare records to hospitals in the same region, therefore avoiding tolerance failure. In addition, following consideration of the hazards of security brought by complicated data intensive activities and processes. Developing a Peer to Peer system to shorten the route of data flows is a common workaround. Another key design feature is letting patients having sufficient autonomy over their own genetic healthcare data. In so doing, patients will be able to access, authorize and account for their healthcare information. This solves the problem of data-transparency for the patients. Finally, there should be a trusted authority to audit the whole process, and each chain of transactions should be recorded carefully to clarify the accountability of the process (Caulfield et al. 2008). As per SSM guidelines, a CATWOE schema is given as Table 1 below to describe the stakeholders and the relationships in the designed system visibly:

Table 1. CATWOE model - Design of Block-chained Precision Healthcare

Clients	Patients
Actors	Patients/Precision Healthcare Service Corporations/Ministry of Health/GP/Hospital/
Transformation	Patient-centered informed consent management. From centralized database to distributed network. Integrating genetic information to healthcare records. Transparent, open, traceable, accountable healthcare record transaction.
World View	Improving the security, data transparency and accountability. Enhancing patients opting in to the precision healthcare to enlarge the network effect of precision health.
Owner	Ministry of Health / Policy-Maker & Regulator
Environment Constraints	Law and Ethical Concern/Technology Support

Architecture

The main reason why blockchain is considered as a secure data storage tool is that it is tamper-proof, decentralized, and transparent. And it is also efficient as it is real-time (Swan 2015). And all of the specialties are related to its working principles. In the conventional HER, there is always a central authority taking the responsibility for recording and updating information. A blockchain is totally different; control is decentralized and all players will be involved in the information system. After a transaction (eg. consultation or lab test), some records would be updated or added. The system will choose the quickest server to perform the action and a copy will be forwarded to others in the system with a link to the previous ledger. Any player can initiate this action and all will have the comprehensive records. When a patient consents to a particular change, it will also be recorded and transformed on the public ledger. The process is also irreversible. With blockchain, genetic information and other medical

information will be hashed and stored in blocks. The secure structure will enhance the security-level of all the data. With genetic-sequence based precision health, the DNA code could also serve as the public key.

Smart Contract

The Smart Contract is an extension of traditional contracts in the digital era. Smart contract was defined as systems which automatically move digital assets, including information, depending on pre-specified rules (Buterin 2014). All the terms of the contract may be encrypted with Blockchain technology. The smart contract is altered with the traditional ones as they do not rely on the trust of players but the open, transparent and non-retractable nature of the scheme. More important than trust therefore is the encryption key. The codes forming the contract may be audited to guarantee fairness and compliance.

Processes and Activities for Block-chained Precision Healthcare

The proposed solution for precision healthcare is developed over the structure of Blockchain and Smart Contract. The key target of the model is to improve patients' autonomy in the whole data processing. To achieve this, the Smart Informed Consent (SIC) system is proposed, with the idea of self-executing script of Smart Contract. This will build a distributed, open, auditable, network for information interoperability with security. This will enhance opting-in and promote greater data participation. Figure 4 shows a content example of SIC of a patient.

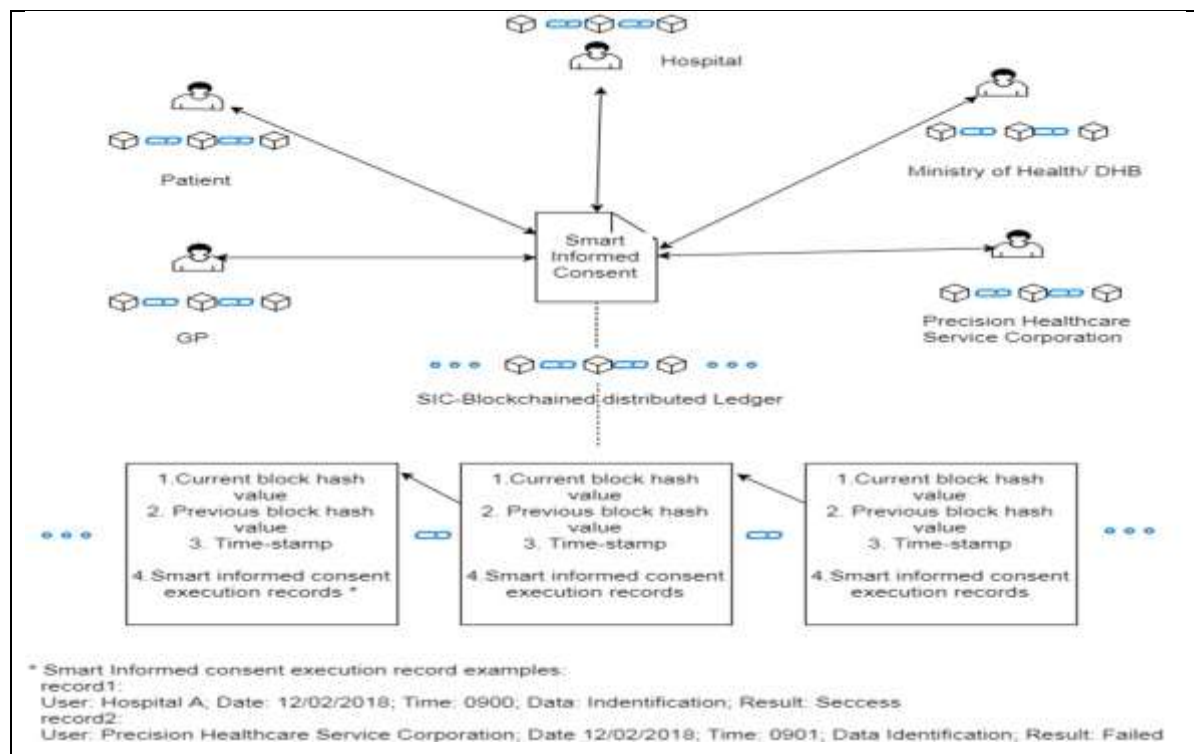


Figure 4. The Smart Informed Consent Activity Diagram

Research in Progress

Drawing from the guidelines of design research, where experts and novices are sought for their comments and insights, we are currently conducting such design interview sessions. Specifically, our design input has been collected from patients, practitioners (nurses, doctors, clinicians), administrators (clinics, hospitals) and policy makers (Health Boards, MoH) reviewing four scenarios in which blockchains would support the security, transparency and accountability of the health ecosystem: 1) registering a smart contract; 2) seeking clinical services; 3) model-building and validation; and 4) performance monitoring. In the manner informed by design research (Peffer et al, 2008), the final activity schemas shall be presented at PACIS 2018 and in a forthcoming paper.

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